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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,703	09/09/2003	Alice Marie Pebay	P08048US00/BAS	6086

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EXAMINER	
GAMETT, DANIEL C	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,703	PEBAY ET AL.	
	Examiner	Art Unit	
	Daniel C Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,4-9, 13-16, 41, 63, 66-70,79, 82-86, 90-93, drawn to a method of modulating spontaneous differentiation of a stem cell comprising incubating the stem cell in the presence of an agonist of a LPL receptor, classified in class 435, subclass 377.

II. Claims 2,10-12, 64, 71-77, 80, 87-89, and 94, drawn to a method for modulating spontaneous differentiation of a stem cell, which method comprises incubating the stem cell in the presence of a ligand of a class III tyrosine kinase receptor, classified in class 435, subclass 377.

III. Claims 3, 65, 81, and 95, drawn to a method for modulating spontaneous differentiation of a stem cell, which method comprises incubating the stem cell in the presence of an agonist of a LPL receptor and a ligand of a class III tyrosine kinase receptor classified in class 435, subclass 377.

IV. Claims 17, 20-26,34-38, drawn to a serum free or substantially serum free medium useful for modulating spontaneous differentiation of a stem cell, comprising an agonist of a LPL receptor, classified in class 435, subclass 405.

V. Claims 18, 27-29, 39, and 40, drawn to serum free or substantially serum free medium useful for modulating spontaneous differentiation of a stem cell,

comprising a ligand of a class III tyrosine kinase receptor, classified in class 435, subclass 406.

VI. Claims 19, 30-33, drawn to a serum free or substantially serum free medium useful for modulating spontaneous differentiation of a stem cell, comprising an agonist of a LPL receptor and a ligand of a class III tyrosine kinase receptor, classified in class 435, subclass 404.

VII. Claims 42-44, and 78, drawn to a stem cell grown and/or maintained in a substantially serum free cell culture medium comprising an agonist of a LPL receptor, classified in class 435, subclass 325.

VIII. Claims 45, 48-53, 57-60, 96, drawn to a method of treating or preventing a disorder of stem cell differentiation comprising administering a composition containing an agonist of a LPL receptor, classified in class 514, subclass 7.

IX. Claims 46, 54-56, 97, drawn to a method of treating or preventing a disorder of stem cell differentiation comprising administering a composition containing a ligand of a class III tyrosine kinase receptor, classified in class 514, subclass 2.

X. Claims 47 and 98, drawn to a method of treating or preventing a disorder of stem cell differentiation comprising administering a composition containing an agonist of a LPL receptor and a ligand of a class III tyrosine kinase receptor, classified in class 514, subclass 2.

XI. Claims 61 and 62, drawn to a pharmaceutical composition comprising a class III tyrosine kinase receptor ligand and/or a LPL receptor agonist, classified in class 424, subclass 198.1.

XII. Claims 99, 101,102,106-108, drawn to a method of identifying a compound capable of modulating spontaneous differentiation of a stem cell by determining binding of a test compound to a LPL receptor, classified in class 435, subclass 7.1.

XIII. Claims 100, 103-105, drawn to a method of identifying a compound capable of modulating spontaneous differentiation of a stem cell by determining binding of a test compound to a class III tyrosine kinase receptor, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups IV and I, Groups V and II, and Groups VI and III, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each pair of inventions includes a product (medium; IV, V, VI) that could be used in processes of modulating the differentiation of a stem cell (I, II, III). Said processes can be practiced with products materially different from the media of Inventions IV, V, or VI. For example, incubation with the appropriate agonist need not take place in culture or in the absence of serum. Conversely, the products of Inventions IV, V, and VI can be used for processes other than to modulate the differentiation of stem cells.

3. Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention VII, a proliferating stem cell, can be obtained by processes other than the process of Invention I.
4. Invention XI and each of I, II, III, VIII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention XI, pharmaceutical composition comprising a class III tyrosine kinase receptor ligand and/or a LPL receptor agonist, could be used for processes other than modulating stem cell differentiation as in Inventions I-III or the treatment or prevention a disorder of stem cell differentiation, as in Inventions VIII-X. Furthermore, the modulation methods of Inventions I-III and the treatment processes of Inventions VIII-X are each materially different because, within each group, each process utilizes a distinct embodiment the pharmaceutical composition of Invention XI.
5. Inventions IV-VII and XI are patentably distinct products. For example, the claimed culture medium of Invention IV contains an agonist of a LPL receptor only, which is not required by any of the other products. Invention V comprises a culture medium containing a ligand of a class III tyrosine kinase receptor only, which is not required by any of the other products.

Invention VI comprises a culture medium containing both a ligand of a class III tyrosine kinase receptor and an agonist of a LPL receptor, which is not required by any of the other products. Invention XI is a pharmaceutical composition, which therefore requires suitability for administration *in vivo*, and further may contain either or both a ligand of a class III tyrosine kinase receptor and an agonist of a LPL receptor, neither of which are required by any of the other products. Invention VII is a cell, which is materially and functionally distinct from any of the other products. Furthermore, searching the inventions of Groups IV-VII and XI together would impose a serious search burden. In the instant case the search of these inventions are not coextensive and each requires an extensive analysis of the art.

6. Inventions V/VI and I are unrelated because the products of Groups V and VI are not used or otherwise involved in the process of Group I.
7. Inventions IV/VI-VII and II are unrelated because the products of Groups IV/VI-VII are not used or otherwise involved in the process of Group II.
8. Inventions IV-V/VII and III are unrelated because the products of Groups IV-V/VII are not used or otherwise involved in the process of Group III.
9. Inventions IV-VII and VIII-X/XII-XIII are unrelated because the products of Groups IV-VII are not used or otherwise involved in the processes of Groups VIII-X/XII-XIII.
10. Inventions XI and XII/XIII are unrelated because the product of Group XI is not used or otherwise involved in the processes of Groups XII/XIII.
11. Inventions I-III, VIII-X, and XII-XIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case, Inventions I-III, VIII-X, and XII-XIII are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Among Inventions I-III, Inventions I and II utilize non-overlapping sets of modulators of cell differentiation, each with its own effects and each with its own non-coextensive search requirements. The combination of agents in Invention III is distinct from either of I or II because of unpredictable interactions that may be interfering or synergistic, leading to different net effects. Inventions VIII-X differ from one another similarly to I-III and collectively they differ from I-III by comprising the additional step of in vivo administration and different effects of treatment or prevention of disorders. Binding assays XII and XIII are distinct from one another by utilizing different ligands and receptors and collectively they differ from Groups I-III and VIII-X by comprising the recited step of determining binding. The different steps, functions, and effects of Inventions I-III, VIII-X, and XII-XIII would require a search for each invention that is non-coextensive with that of any other invention and therefore searching any combination of Inventions I-III, VIII-X, and XII-XIII together would impose a serious search burden.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for any of Group I-XIII is not required for any other of Group I-XIII, restriction for examination purposes as indicated is proper.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

DCG
Art Unit 1647
3 March 2005